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MAY - 2 2012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	ZELTIQ™ Aesthetics, Inc. 4698 Willow Road Pleasanton, CA 94588
TRADE NAME:	ZELTIQ CoolSculpting
COMMON NAME:	Skin Cooling Device
CLASSIFICATION NAME:	Contact Cooling System for Aesthetic Use
DEVICE CLASSIFICATION:	Class II, 21 CFR §878.4340
PRODUCT CODE:	OOK
PREDICATE DEVICE:	The ZELTIQ CoolSculpting device is substantially equivalent to the ZELTIQ Dermal Cooling Device, cleared as K080521, and also known as the ZELTIQ Lipolysis System and the ZELTIQ System (K090094).

SUBSTANTIALLY EQUIVALENT TO:
The ZELTIQ CoolSculpting System is substantially equivalent to the ZELTIQ Dermal Cooling Device (K080521), also known as the ZELTIQ CoolSculpting System, which has been cleared for the indication of cold-assisted lipolysis of the flank (love handle). It is also substantially equivalent to the ZELTIQ System (K090094) which has been cleared for the indication of a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The CoolSculpting System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device includes an optional massage feature.

INDICATION FOR USE:
The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis of abdomen, as well as the flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of the abdomen and the flank. Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatments and act as a local anesthetic for procedures that induce minor local discomfort.

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The CoolSculpting System is also indicated for use to provide localized thermal therapy (hot or cold) to minimize pain post-trauma and post-surgery, and for temporary relief of minor aches, pains, and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.
The ZELTIQ Gelpad facilitates thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:
The CoolSculpting System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also provides an optional massage feature.

PERFORMANCE DATA:

Animal data has been used to establish device safety and preferential selectivity of the CoolSculpting System for fat cells without damaging surrounding normal skin and muscle.

CLINICAL PERFORMANCE:

A prospective multicenter clinical study was conducted to evaluate the use of the ZELTIQ System for subcutaneous fat reduction in the abdominal area. Sixty (60) subjects were treated with the ZELTIQ System at CIF 42 (a Cooling Intensity Factor setting of 42 corresponds to 72.9 mW/cm^2 of heat extracted from the body) over 60 minutes. The optional massage feature was not used as part of this study.

The primary endpoint was the photographic evaluation by three independent blinded evaluators at the 16 week follow-up. The evaluators correctly identified the baseline image 85% of the time and the result was statistically significant. Fat layer reduction in the abdomen was further confirmed by overall positive patient survey results and statistically significant ultrasound results. Lipid profile and liver function tests conducted at several points post-treatment showed no discernible difference from baseline. No serious adverse events were reported. Results from the clinical study support safe and effective use of the device for cold-assisted lipolysis of the abdomen.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:
Clinical testing has demonstrated the ability of the CoolSculpting System to cause lipolysis of the subcutaneous fat in the abdomen in the same way that lipolysis occurs when the device is used in the flank. The device is used in the same way and with equivalent settings and use parameters as when used for treatment of the flank.

There has been no substantial change to the device design or operating principles from those of the previously cleared device for a similar indication. For that reason, bench testing was not required to demonstrate that the device is functionally equivalent to the predicate devices regarding design or operating principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ZELTIQ Aesthetics, Inc.
% Mr. Louis-Pierre Marcoux
Director of Regulatory Affairs
4698 Willow Road
Pleasanton, California 94115

JUN - 1 2012

Re: K120023
Trade/Device Name: ZELTIQ CoolSculpting
Regulation Number: 21 CFR 878.4340
Regulation Name: Contact cooling system for aesthetic use
Regulatory Class: II
Product Code: OOK
Dated: April 20, 2012
Received: April 23, 2012

Dear Mr. Marcoux:

This letter corrects our substantially equivalent letter of May 2, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K120023**

Device Name: ZELTIQ CoolSculpting

Indications for Use:

The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis of the abdomen, as well as the flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of the abdomen and the flank. Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatments and act as a local anesthetic for procedures that induce minor local discomfort.

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The ZELTIQ Gelpad facilitates thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.

Prescription Use _x_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120023